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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,409	09/16/2003	J. David Brown	600.592US1	1761

21186 7590 07/05/2006

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/664,409		BROWN ET AL.	
	Examiner		Art Unit	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-75 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 50-56 and 61-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-49 and 57-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group III in the reply filed on 6 April 2006 is acknowledged. The traversal is on the ground(s) that the common classification of the claims renders the inventions similar in scope and examination of all the claims together is not a serious burden on the office. This is not found persuasive because applicant is entitled to a single invention per application. Unless applicant agrees that the inventions contained within the present application are not patentably distinct, examiner has determined that the additional components found in various embodiments of the device constitute separately patentable inventions that should be examined separately.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to because the drawing comprise stray markings such as copy machine marks and sometimes unclear handwritten annotations. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes

made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 17-21, 26, 27, 29-33, 36-46, and 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,167,615 to East et al.

In the specification and the figures, East discloses the device as claimed by applicant. With regard to claims 17-21, 29, and 33, East discloses an implantable shunt device with a flow controller comprising an inlet flow channel 38 and flow resistors or valves 26, 28 that are opened or closed to provide a first and second resistance to flow (see column 5, lines 20-65). When both valves are open, the resistance to flow is less than when one valve is closed. The modes are percutaneously selectable, meeting applicant's claim limitation drawn to a "remotely selectable" mode. A first discharge port

or fluid conduit 34 passes through both valves, creating a particular resistance to flow when the valves are open or closed. A second fluid conduit 36 bypasses the first valve, creating separate discharge ports with differing resistances—high when the valves are closed, and low when the valves are open.

With regard to claims 26, 27, 32, 37, 45, 46, and 57-60, the flow controller includes a plug 104 and a percutaneously actuatable cam 114 with a magnetic material 116 (thereby encompassing ferromagnetic particles), meeting the limitations of the claim (see column 9, lines 29-50). When the magnet is activated, it opens or closes the valve by moving the plug, adjusting the resistance from a first state to a second state.

With regard to claims 30, 31, 36, 38, 39, 40, 42, and applicant's recitations drawn to the operation of the flow controller, such limitations are held to be a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the flow controller disclosed by East is capable of opening and closing the valves in the device to create a first and second resistance to flow as claimed by applicant, thereby meeting the limitations of the claims.

With regard to claims 41, 43, and 44, the valves may comprise a membrane 100 (see column 8, lines 65-67) and a membrane supports 40, 44, 48 that exert a "first tension" on the membrane by maintaining it in a selected position. With regard to applicant's recitation of the operation of the support and selection of a second mode, such limitations are held to be a statement of the intended use of the device. It has been

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held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the removal of any of the membrane supports (which are equivalent to applicant's recitation of a plurality of pins—that is, devices that serve as a support for another article (see Merriam-Webster's Collegiate Dictionary, 10th Ed., 2001)) would affect the resilience, tension, and action of the membrane in the flow controller. Therefore, the device disclosed by East is capable of operating as claimed by applicant and meets the limitations of the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22-25, 34, 35, and 47-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,167,615 to East et al in view of US 5,300,020 to L'Esperance.

In the specification and figures, East discloses the device substantially as claimed by applicant (see rejection above) with the exception of a biodegradable polymer. L'Esperance discloses an implantable device for fluid flow control that comprises a porous biodegradable plug or flow resistor 16 that controls fluid flow through the shunt device 10 (see column 3, lines 20-40). The plug dissolves upon

lengthy contact with tissue elements (which includes enzymes) at body temperature, and may be made of polyglycolic acid (see column 7, lines 40-48). The dissolving plug allows the eye to heal from shunt insertion before the shunt begins to convey fluid. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a biodegradable polymer as a plug as disclosed by L'Esperance in one of the passages of the flow control device disclosed by East, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

7. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,167,615 to East et al in view of US 4,886,488 to White.

In the specification and figures, East discloses the device substantially as claimed by applicant (see rejection above) with the exception of using gold as a material component of the flow controller. White discloses a glaucoma drainage shunt that may be made of gold due to its biological acceptance (see column 3, lines 50-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use gold as disclosed by White in the flow controller disclosed by East, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

Conclusion

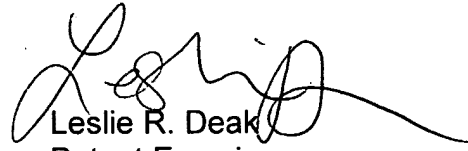
8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 5,178,604 Baerveldt et al
 - i. Glaucoma implant with two outlets and dissolving plug
- b. US 6,162,238 Kaplan et al
 - ii. Device for controlling flow through body lumens
 - iii.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
24 June 2006

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

